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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,336

03/21/2005

Lars Branden

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

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DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/505,336	Applicant(s) BRANDEN ET AL.	
	Examiner FRANK W. LU	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23, 25-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group B, claims 25-28 in the reply filed on December 17, 2007 is acknowledged. The traversal is on the ground(s) that: (1) "[P]CT Rule 13.2 in Part Ib of the Annex B of the administrative instructions under the PCT specifies that 'special technical features' is defined as meaning those features that define the contribution which each of the inventions, considered as a whole, makes over the prior art. Thus, PCT Rule 13.2 requires the citation of a publication showing the 'special technical feature'. There is no citation of a publication in the outstanding Official Action, and the publication cited in the Official Action of June 20, 2007 fails to disclose the subject matter of the pending claims. Therefore, absent any showing that the 'special technical feature' shared by the pending claims 21-23, 25-28, and 30 is present in a prior art publication, no determination of lack of unity can properly be made as a matter of law. Moreover, applicants respectfully submit that there is unity of invention as the biomolecular complex produced in claims recited in claims 21-23 and 30. Furthermore, as previously stated in the amendment filed August 20, 2007, the International Searching Authority did not determine the unity of invention as lacking in applying this same legal standard with similar claims. It is still not clear as to why a different legal conclusion was reached with respect to PCT Rule 13.2. In view of the above, it is believed that the lack of unity determination set forth in the Official Action is improper as a matter of law and should be withdrawn".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of

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same such that Groups A and B will be examined. First, since Groups A and B are directed to two different methods and they do not share a special technical feature as argued by applicant, the examiner does not require to cite a publication as a prior art. Second, Groups A and B distinguish from each other. For example, the study of inter-molecular interactions under physiological or near-physiological conditions in claim 21 of Group A is not required for Group III while the production of a biomolecular complex recited in claim 25 of Group B is not required for Group I. Therefore, Groups A and B do not relate to a single general inventive concept under PCT Rule 13.1 and the requirement is still deemed proper and is made FINAL. Since claim 30 is dependent on claim 25, claims 25-28 and 30 will be examined.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the inventor, Edvard Smith, changed his address without an initial. See 37 CFR 1.52(c).

Specification

3. The abstract of the disclosure is objected to because the abstract contains the phrase such as “[T]he present invention concerns”. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the

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printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The disclosure is objected to because of the following informality: there are several nucleotide sequences having 10 nucleotides in Figure 2. However, Figure 2 does not have SEQ ID NOs for these nucleotide sequences or short description of the drawings of the specification related to Figure 2 does not describe SEQ ID NOs for these nucleotide sequences (see page 4 of the specification).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25-28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 25 is rejected as vague and indefinite in view of the preamble because it is unclear that "each FE" in line 4 means each of FE₁ and FE₂ or means each of FE₁, FE₂, FE_n. Please clarify.

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8. Claim 25 recites the limitation “the corresponding sequence” in lines 6 and 7 of the preamble. There is insufficient antecedent basis for this limitation in the claim because there is no “corresponding sequence” before “the corresponding sequence”. Please clarify.
9. Claim 25 is rejected as vague and indefinite in view of the preamble because it is unclear that “the target molecules or areas” in line 7 means the target molecule or area which attaches to FE₁ or means the target molecule or area which attaches to FE₂ or means the target molecules or areas which attaches to FE₁ and FE₂. Please clarify.
10. Claim 25 is rejected as vague and indefinite in view of “said linkers” in line 9 of the preamble. Since the second linker is optional, it is unclear that “said linkers” means a first linker or means a second linker or means a first linker and a second linker. Please clarify.
11. Claim 25 is rejected as vague and indefinite in view of step d) because it is unclear that each solution is from separate solutions or not. Please clarify.
12. Claim 25 is rejected as vague and indefinite in view of step e) because it is unclear that at least one binding entity is from at least two binding entities of step c) or not. Please clarify.
13. Claim 25 is rejected as vague and indefinite in view of step f) because it is unclear that at least one binding entity is from at least two binding entities of step c) or not. Please clarify.
14. Claim 25 is rejected as vague and indefinite in view of step g) because it is unclear that each functional entity is from said first functional entity and said second functional entity or not. Please clarify.
15. Claim 25 is rejected as vague and indefinite in view of step h) because it is unclear that each linker molecule is from what linker molecules. Furthermore, it is unclear that at least two

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target molecules/target areas are identical to the target molecules or areas in the preamble or not.

Please clarify.

16. Claim 25 rejected as vague and indefinite in view of step i) because it is unclear that each linker in step i) is identical to each linker molecule in step h) or not. Furthermore, it is unclear that each combination of functional entity and binding entity is from which combinations of functional entity and binding entity. Please clarify.

17. Claim 25 is rejected as vague and indefinite in view of step j) because it is unclear why repeating step h) can form a library of combinations of functional entities and linkers. Please clarify.

18. Claim 25 or 26 is rejected as vague and indefinite. Although the preamble contains functional elements and binding elements, there are no functional elements and binding elements in the contents of the claim and the contents of the claim only contain the first and second functional entities and two different binding entities. Therefore, it is unclear what is the relationship between functional elements and binding elements in the preamble and the first and second functional entities and two different binding entities in the content of the claim. Please clarify.

19. Claim 25 or 26 is rejected as vague and indefinite. Although the claim is directed to a method for the production of a biomolecular complex comprising at least two functional elements (FE₁, FE₂) each attached to a target molecule or area (T) through binding elements (BE), there is no method step for producing a biomolecular complex comprising at least two functional elements (FE₁, FE₂) and the goal of the claim cannot be reached. Please clarify.

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20. Claim 26 is rejected as vague and indefinite in view of the preamble because it is unclear that “each FE” in line 3 means each of FE_1 and FE_2 or means each of FE_1 , FE_2 , FE_n . Please clarify.

21. Claim 26 recites the limitation “the corresponding sequence” in lines 6 and 7 of the preamble. There is insufficient antecedent basis for this limitation in the claim because there is no “corresponding sequence” before “the corresponding sequence”. Please clarify.

22. Claim 26 is rejected as vague and indefinite in view of the preamble because it is unclear that “the target molecules or areas” in line 7 means the target molecule or area which attaches to FE_1 or means the target molecule or area which attaches to FE_2 or means the target molecules or areas which attaches to FE_1 and FE_2 . Please clarify.

23. Claim 26 is rejected as vague and indefinite in view of “said linkers” in line 9 of the preamble. Since the second linker is optional, it is unclear that “said linkers” means a first linker or a second linker or means a first linker and a second linker. Please clarify.

24. Claim 26 recites the limitation “the desired configuration” in step vi) of the preamble. There is insufficient antecedent basis for this limitation in the claim because there is no “desired configuration” before “the desired configuration”. Please clarify.

25. Claim 26 is rejected as vague and indefinite in view of step vi) because it is unclear what are “these”. Furthermore, it is unclear that said linker in solution means a first linker or a second linker in the preamble or a linker in step v). Please clarify.

26. Claim 27 is rejected as vague and indefinite because it is unclear that the linker molecule means a first linker or a second linker in the preamble or a linker in step v). Please clarify.

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27. Claim 28 is rejected as vague and indefinite because it is unclear that the binding entities are the first binding entities or the second binding entities or both the first binding entities and the second binding entities. Please clarify.

28. Claim 30 is rejected as vague and indefinite because it is unclear that the functional entities are the first functional entities or the second functional entities or both the first functional entities and the second functional entities. Please clarify.

Conclusion

29. No claim is allowed.

30. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Frank W Lu /
Primary Examiner, Art Unit 1634
March 12, 2008

<div><div><div>Application Number</div><div></div></div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/505,336	BRANDEN ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	